

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. DISPOSITION OF THE CLAIMS

Claims 43-44 are requested to be cancelled.

Claim 30 is currently being amended.

Claim 61 is being added.

This amendment adds no new matter. Support for the amendment and new claim 61 are found on the paragraph [0035] and in the Example 1 of the published version of the present application, US 2007/0009598.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 30-31, 33-42, and 45-61 are now pending in this application. Claims 54-60 are withdrawn as non-elected.

II. AMENDMENT OF CLAIMS

Claim 30 is amended to delete “at least a polymer or” in the definition of the water-repellent intermediate layer.

Claim 30 is amended by adding the term “chosen from partially hydrogenated oils, beeswax, carnauba wax, paraffin waxes, silicone waxes, C12-C18 fatty alcohols and fatty acids, solid, semi-synthetic glycerides, glycerol monoesters, diesters or triesters, polyoxyethylene glycols and glycosylated polyoxyethylenated glycerides, monostearate glycerides and mixtures thereof”, after thermoplastic excipient.

The claims stand rejected under 35 USC § 103(a) as being unpatentable over US 2004/081691 (“Debregeas”) in view of O’Hara (Arch. Family Ivied 1998).

Debregeas discloses plant-containing microgranules comprising:

- 1) a neutral core [0022]-[0023]
- 2) a layer, coating said neutral core, containing the plant extract [0021] and, optionally, a binder [0024]
- 3) an outer polymeric layer intended i) to mask the taste and/or the odour of the plant substance, ii) to delay its release or iii) to control its release [0025]

On the other hand, the microgranules of the present invention comprise:

- 1) a neutral core,
- 2) a layer coating the neutral core, said layer containing Ginkgo biloba extract with at least one pharmaceutically acceptable excipient,
- 3) a water-repellent intermediate layer, coating said core, comprising a thermoplastic excipient, and
- 4) an outer polymeric layer which sustains the release of said extract from the active core.

The Examiner asserted that it would have been obvious to one skilled in the art at the time the invention was made to prepare such granules using two or more of these coatings as each are commonly employed in the art for their known individual modifying benefits including with respect to providing stability, long-term sustained effectiveness, and /or taste or odor-masking qualities thereto.

Also, the Examiner asserts that the binder layer (e.g comprising water-repellent PVP) reasonably reads upon a water-repellent intermediate layer,

Applicant respectfully traverses the latter point for the following reasons. Contrary to the Examiner's assertion, PVP cannot be considered to be a water-repellent excipient.

To the contrary, PVP is a hygroscopic excipient and is not water-repellent. In support, Applicants quote from the Handbook of Pharmaceutical Excipients (2000) ("Handbook"), which Applicants submit in an Information Disclosure Statement. The Handbook provides the specifications of crospovidone and croscarmellose. At page 508, point 8, the Handbook state that "Povidone is a white to creamy-white, odourless or almost odourless, hygroscopic powder." At page 509, point 10 on solubility, the Handbook states that "Povidone is freely soluble in water."

Therefore, contrary to what the Examiner states, PVP cannot be considered as a water-repellent excipient.

In fact, the intermediate layer of the present invention has been added to avoid the problem of sticking between granules that is induced by the Ginkgo Biloba extract, and to ensure a good stability over time. Table 6 (accelerated stability study) describes an investigation of the physical stability of Ginkgo Biloba sustained release dosage forms prepared with an intermediate water-repellent layer. The formulations were stored for 3 months under controlled conditions of relative humidity (RH/75%) and temperature (40°C). It was found that Ginkgo Biloba in the sustained release formulations prepared with an intermediate water-repellent layer was chemically stable against the effects of temperature and humidity.

The objective problem which was posed and solved by the present invention was thus to provide microgranules containing Ginkgo biloba extract that were i) not sticky and ii) stable over time.

Concerning this point, Debregeas does not solve this technical problem nor suggest that sustained release microgranules of Ginkgo Biloba or any other active principle having an intermediate water-repellent layer located between the active layer and the sustained-released layer would solve it.

Therefore, one skilled in the art would not have been motivated to use an intermediate water-repellent layer in Ginkgo Biloba sustained release dosage forms, as presently claimed, because no document from the prior art taught or suggested that the addition of a water-repellent intermediate layer located between the active layer and the sustained-released layer would solve this problem.

Thus, it was not obvious, for a person of ordinary skill in the art, to have the idea to add such a water-repellent layer, which has never been described, to solve the above-mentioned problem.

Accordingly, Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 8-DEC-2008

By 

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